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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/534,357

02/21/2006

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YOUDIM1.1A

4865

1444 7590 01/09/2009
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EXAMINER

DAVIS, ZINNA NORTINGTON

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

01/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,357	Applicant(s) YOUDIM ET AL.	
	Examiner Zinna Northington Davis	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-60, 79-94, 96-134, 136 and 138-140 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-60, 79-94, 96-134, 136, and 138-140 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Election/Restrictions

1. Claims 1-60, 79-94, 96-134, 136, and 138-140 are pending. Claims 61-78, 95, 135, and 137 have been cancelled.
2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-60, and 99-109, drawn to a chemical compound selected from a residue that imparts a neuroprotective function in a compound and a pharmaceutical composition which can be further restricted based upon the residue.
 - II. Claims 79-94, 110-128, drawn to a method for iron chelation therapy using a chemical compound of claim 1 which can be further restricted based upon the residue.
 - III. Claim 96, drawn to a method for iron chelation therapy using the chemical compound, 5-[4-(2-hydroxyethyl)piperazin-1-ylmethyl]-8-hydroxyquinoline.
 - IV. Claim 97, drawn to a cosmetic composition for topical application using the chemical compound, 5-[4-(2-hydroxyethyl)piperazin-1-ylmethyl]-8-hydroxyquinoline.
 - V. Claim 98, drawn to a method for preservation of organs intended for transplantation using the chemical compound, 5-[4-(2-hydroxyethyl)piperazin-1-ylmethyl]-8-hydroxyquinoline.
 - VI. Claims 129, 131-132, and 134, drawn to a method for prevention of a neurodegenerative or cerebrovascular disease, condition or disorder using

a chemical compound of claim 1 which can be further restricted based upon the residue.

- VII. Claims 129, 131-132, and 134, drawn to a method for treatment of a neurodegenerative or cerebrovascular disease, condition or disorder using a chemical compound of claim 1 which can be further restricted based upon the residue.
- VIII. Claims 130 and 133, drawn to a method for prevention of a neurodegenerative or cerebrovascular disease, condition or disorder using the chemical compound, 5-[4-(2-hydroxyethyl)piperazin-1-ylmethyl]-8-hydroxyquinoline.
- IX. Claims 130 and 133, drawn to a method for treatment of a neurodegenerative or cerebrovascular disease, condition or disorder using the chemical compound, 5-[4-(2-hydroxyethyl)piperazin-1-ylmethyl]-8-hydroxyquinoline.
- X. Claim 136, drawn to a method for treatment of skin disease using a chemical compound of claim 38 which can be further restricted based upon the residue.
- XI. Claim 138, drawn to a method for preservation of an organ intended for transplantation using a chemical compound of claim 38.
- XII. Claims 139-140, drawn to a method for the treatment of a disease, disorder, or condition using the chemical compound, 5-[4-(2-hydroxyethyl)piperazin-1-ylmethyl]-8-hydroxyquinoline.

XIII. Claims 139-140, drawn to a method for the prevention of a disease, disorder, or condition using the chemical compound, 5-[4-(2-hydroxyethyl)piperazin-1-ylmethyl]-8-hydroxyquinoline.

3. Inventions I-XIII are related as product claims. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. For instance, see the method claims.
4. This application contains claims directed to the following patentably distinct species of the claimed invention: the residue and R.

The ring system and radicals within the definition of the residue are diverse in scope. A prior art reference, which anticipates one member such as pyridine-4-one under 35 U.S.C. 102, would not render obvious another member such as pyridinyl or quinoline under 35 U.S.C. 103. Accordingly, the ring systems and the radicals are independent and patentably distinct.

5. Applicant is required under 35 U.S.C. § 121 to elect **a single disclosed species** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. If the preferred group is a method of use, a single disclosed disease state should be elected.
6. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above

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and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) The inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (b) The inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (c) The prior art applicable to one invention would not likely be applicable to another invention; and
- (d) The inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after

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the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

8. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

10. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

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be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

11. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Due to the complexity of the restriction requirement, a written request is made.

13. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by

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a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna N. Davis whose telephone number is 571-272-0682. The examiner can normally be reached on M-F.

16. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Zinna Northington Davis/
Zinna Northington Davis
Primary Examiner
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